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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,989	03/20/2000	Jean Marie Vogel	9676-292	6000

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EXAMINER	
WELLS, LAUREN Q	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/528,989	VOGEL ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *5,6,9,10 and 21-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8 and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *22* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-51 are pending. Claims 5-6, 9-10, and 21-51 are withdrawn from consideration, as they are directed to non-elected subject matter. The Amendment filed 3/25/02, Paper No. 15, amended claims 1, 21 and 47.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/29/02 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

Applicant's election with traverse of the Restriction and Election of Species Requirement in Paper No. 21 is acknowledged. The traversal is on the ground(s) that a single search would encompass the claims as currently presented. This is not found persuasive, as a kit is not related to a composition or a method, and the search of a method of use does not encompass a search for a composition with specific constituents. Furthermore, regarding the election of species, it is respectfully pointed out that the microspheres can comprise a great number of compounds, the carrier can comprise a great number of compositions, and the cross-linker can comprise a great

number of compounds. Thus, a search of every possible combination of microsphere, carrier, and cross-linker would be a serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7-8 and 11-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-9, 12, 13-19 of U.S. Patent No. 6,436424. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant invention recites a composition comprising biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microspheres and a biocompatible carrier, wherein said composition is injectable through needles of about 18 to 26 gauge and wherein said microspheres swell to a predetermined size after injection within the non-dermal tissue of said mammal. It is further recited, in a dependent claim that the average diameters of the microspheres after injection are about 1 to 4 times of average diameters of microspheres immediately prior to injection.

'424 teaches a composition comprising a biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microsphere and a biocompatible carrier, wherein said composition is injectable through needles of about 30 gauge or smaller, wherein the microspheres swell upon contacting with physiological fluids at injection site, and wherein average diameters of the microspheres after injection are about one to four times of average diameters of microspheres immediately prior to injection.

'424 does not teach needles of about 18-26 gauge. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of '424 to teaches needles of about 18-26 gauge for administration because '424 teaches that the composition is injectable through needles less than or equal to 30 gauge and an 18-26 gauge is less than a 30 gauge.

Claims 1-4, 7-8, 11-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-8, 11-20 of copending Application No. 10/222,819. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant invention recites a composition comprising biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microspheres and a biocompatible carrier, wherein said composition is injectable through needles of about 18 to 26 gauge and wherein said microspheres swell to a predetermined size after injection within the non-dermal tissue of said mammal.

'819 teaches a composition comprising a biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microsphere and a biocompatible carrier, wherein said

composition is injectable through needles of about 30 gauge or smaller, wherein the microspheres swell upon contacting with physiological fluids at injection site, and wherein average diameters of the microspheres after injection are about one to four times of average diameters of microspheres immediately prior to injection.

'819 does not teach needles of about 18-26 gauge. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of '819 to teaches needles of about 18-26 gauge for administration because '819 teaches that the composition is injectable through needles less than or equal to 30 gauge and an 18-26 gauge is less than a 30 gauge.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "derivative" in claim 12 (line 2) is vague and indefinite, as the metes and bounds of this claim are unascertainable. This term is not defined in the specification and one of skill in the art would not be apprised of all the possible chemical modifications encompassed by this term.

(ii) Claim 20 is vague and indefinite, as it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform that function. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7-8, 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogel et al. (WO 99/44643) in view of Hubbard (5,922,025).

The instant invention is directed toward a composition comprising biocompatible, swellable, hydrophilic, non-toxic and substantially spherical microspheres and a biocompatible carrier.

Vogel et al. teach implantable particles comprising cationic, hydrophilic microparticles and a cell adhesion promoter for tissue bulking and the treatment of gastroesophageal reflux disease, urinary incontinence, and skin wrinkles. The microparticles are pre-coated with autologous cells, such as muscle and fat cells. Hydrophilic copolymers are those of the acrylic family, such as polyacrylamides, polyacrylates, polyallyl compounds, and polyvinyl compounds. It is disclosed that all of these polymers are crosslinked. Spherical microparticles are the preferred shape and 10-1000 micrometers is the preferred diameter. The microparticles are stable in suspension and can be injected with different liquids. Contrast agents, such as barium

or iodine salts, can be added to the microparticles. The microparticles can be injected with anti-inflammatory drugs to decrease local inflammation. The microparticles can be added to aqueous or hydro-organic solutions. Exemplified are compositions comprising 90grams of methylolacrylamide, 2 grams of methacrylamidopropyl-trimethyl-ammonium-chloride hydrochloride and 10 grams of N,N'-methylene-bis acrylamide (cross-linker) added to 10mg/ml anti-inflammatory drug solution in sterile physiological saline. The reference lacks an exemplification and preferred percent weight ranges. See pg. 7, line 25-pg. 14, line 17; pg. 20, line 9-line 32; pg. 22, line 10-pg. 30, line 30.

Hubbard teaches soft tissue augmentation material comprised of spherical particles. The particles are disclosed as ranging in size from 35 to 150 microns and is being injected through an 18 gauge syringe. See Col. 5, lines 1-45.

The Examiner respectfully points out that the phrase, "wherein the composition is injectable through needles of about 18 to 26 gauge" is a future intended use and therefore not afforded patentable weight. However, as evidenced by Hubbard, it would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of Vogel as injectable through an 18 gauge syringe because a)Hubbard and Vogel both teach microspheres for tissue augmentation, and b) the range of the size of microspheres taught by Vogel overlaps the range taught by Hubbard, wherein the size of the microspheres determines the syringe gauge size; thus, one of skill in the art would be motivated to inject the microspheres of Vogel through an 18 gauge syringe because Hubbard teaches that microspheres within the particle size range of Vogel can be administered via an 18 gauge syringe.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the percent weight ranges of cross-linkers, microspheres, and biocompatible carriers of Vogel as that recited in the instant invention because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

NOTE: The phrases, "for tissue bulking in a mammal" and "wherein said composition is injectable through needles of about 18 to 26 gauge and wherein said microspheres swell to a predetermined size after injection within the non-dermal tissue of said mammal" in claim 1 are recitations of intended use. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

It is furthermore respectfully noted that since the above rejection teaches the same microspheres as that of the instant invention, the microspheres of the rejection must share the same swell sizes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
December 19, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER

12/26/02